



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-5570]

Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications for Manufacturers of In Vitro Diagnostic Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications for Manufacturers of In Vitro Diagnostic Devices.” FDA has developed this draft guidance to implement the 21st Century Cures Act (the Cures Act), which requires FDA to revise “Section V. Demonstrating Insignificant Risk of an Erroneous Result--Accuracy” of the guidance “Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices” (“2008 CLIA Waiver Guidance”) that was issued on January 30, 2008. This draft guidance represents FDA’s current thinking regarding “the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy.” The 2008 CLIA Waiver Guidance remains in effect, in its current form, until this draft guidance is finalized, at which time the updates in section III of this draft guidance will supersede the recommendations in section V of the 2008 CLIA Waiver Guidance. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2017-D-5570 for “Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications for Manufacturers of In Vitro Diagnostic Devices.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the

body of your comments and you must identify this information as “confidential.”

Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications for Manufacturers of In Vitro Diagnostic Devices” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Peter Tobin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5657, Silver Spring, MD 20993-0002, 240-402-6169; and Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed this draft guidance to implement section 3057 of the Cures Act (Pub. L. 114-255), which requires FDA to revise “Section V. Demonstrating Insignificant Risk of an Erroneous Result--Accuracy” of the guidance “Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices”¹ (“2008 CLIA Waiver Guidance”) that was issued on January 30, 2008. This draft guidance represents FDA’s current thinking regarding “the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy.” The 2008 CLIA Waiver Guidance remains in effect, in its current form, until this draft guidance is finalized, at which time the updates in section III of this draft guidance will supersede the recommendations in section V of the 2008 CLIA Waiver Guidance.

FDA will incorporate the final version of this draft guidance into “Section V. Demonstrating Insignificant Risk of an Erroneous Result--Accuracy” of the 2008 CLIA Waiver Guidance. The remainder of the 2008 CLIA Waiver Guidance, with exception of technical edits

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<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070890.pdf>.

for consistency with the newly amended section V, will not be substantively changed and will remain in effect.

The Secretary of Health and Human Services has delegated to FDA (69 FR 22849, April 27, 2004) the authority to determine whether particular tests are “simple” and have “an insignificant risk of an erroneous result” under CLIA and thus are eligible for CLIA waiver (42 U.S.C. 263a(d)(3)). The Centers for Medicare & Medicaid Services is responsible for oversight of clinical laboratories, which includes issuing Certificates of Waiver. CLIA requires that clinical laboratories obtain a certificate before accepting materials derived from the human body for laboratory tests (42 U.S.C. 263a(b)).

The 2008 CLIA Waiver Guidance describes recommendations for device manufacturers about study design and analysis for CLIA Waiver by Application to support an FDA determination as to whether the device meets the statutory criteria for waiver (42 U.S.C. 263a(d)(3)).

On November 29, 2017, FDA announced in the *Federal Register* a draft guidance entitled “Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications for Manufacturers of In Vitro Diagnostic Devices” (82 FR 56607). This draft guidance proposed additional approaches for demonstrating that a test meets the criteria in 42 U.S.C. 263a(d)(3)(A). FDA is issuing a revised draft guidance by the same title, after considering comments received on the draft guidance issued November 29, 2017.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Select Updates for Recommendations for Clinical Laboratory Improvement

Amendments of 1988 Waiver Applications for Manufacturers of In Vitro Diagnostic Devices.”

It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This guidance document is also available at <https://www.regulations.gov> or <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. Persons unable to download an electronic copy of “Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications for Manufacturers of In Vitro Diagnostic Devices” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 16046 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR Part; Guidance; or FDA Form	Topic	OMB Control No.
50, 56	Protection of Human Subjects: Informed Consent; Institutional Review Boards	0910-0755
54	Financial Disclosure by Clinical Investigators	0910-0396
812	Investigational Device Exemption	0910-0078
“Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices”	CLIA Waiver Applications	0910-0598
“Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization”	CLIA Categorizations	0910-0607
“Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff”	Q-submissions	0910-0756

Dated: November 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-25959 Filed: 11/28/2018 8:45 am; Publication Date: 11/29/2018]